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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,061

03/29/2006

Mitsuhiro Haraguchi

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7055 7590 06/12/2008
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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

06/12/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/538,061	Applicant(s) HARAGUCHI ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 and 22-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Amendment filed February 29, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

1) Claims 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Busciglio (US 4,748,022).

Applicant's Arguments

Applicant has amended the claims to recite the pH of the compositions are about 3.0 to 7.5. Applicant argues the reference disclose the in contrast Busciglio require a pH of 8-9. This argument is not persuasive.

Examiner's Response

The term "about" permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." Furthermore, where close prior art exists, the normally definite term "about" can become indefinite, with Applicant bearing

the burden of establishing that the term is sufficiently clear to avoid such art. See specifically Amgen v. Chugai, 927 F2d. 1200 (Fed. Cir. 1991). Applicant does not appear to show or argue the difference between about 7.5 as recited in the claims and 8 as recited in the reference. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 15-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Thut et al. (US 5,505,922). The rejection is maintained in regards to claims 15-20 and 22-34.

Applicant's Arguments

Applicant argues a particular parameter must first be recognized as a result-effective variable. The reference fails to teach or suggest using a combination of any amide-type local anesthetic and any antihistamine-like anesthetic such as benadryl. The various types of local anesthetics mentioned in the preceding sentences is not more than a boilerplate statement which neither teaches nor suggests the combination or any advantages associated with the combination. None of the claims in the reference mention an antihistamine-like anesthetic such as benadryl, which indicates that these anesthetics are not particularly preferred. Thut provides no motivation to combine these two components or optimize the ratios. Applicants also disagree with the allegation that there is a well known relationship between isotonicity of a composition and the ability of the compositions to diffuse into a patient's system. This argument is not persuasive.

Examiner's Response

In regards to the ratio, the claims read on a 1:1 ratio of anesthetic and the antihistamine. The term "mixtures" is generally understood to be 1:1. In regards to there is no suggestion of providing a mixture of the recited components. The mere mention of mixing anesthetics and the naming of benadryl specifically suggest mixing benadryl with a local anesthetic or another anesthetic, even if it is considered by Applicant a boilerplate statement. Furthermore the instant claims recite anesthetic and antihistamine generally. Also benadryl is the only example of an antihistamine anesthetic disclosed further supporting the addition of benadryl with another anesthetic. In regards to the relationship between isotonicity of a composition and the ability of the compositions to diffuse into a patient's system, an isotonic agent is a component that controls osmotic pressure¹. Osmotic pressure controls absorption of the drug². This shows a relationship between isotonicity and the ability of the composition to diffuse into the patient's system because by controlling isotonicity, one controls osmotic pressure which controls absorption of the drug.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

1) Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takeuchi et al. (US 5,624,962).

¹ Haraguchi et al. 6,008,256, col. 6, lines 28-44.

Takeuchi et al. disclose drug compositions having the property of reversible thermosetting gelation that may be used in the oral cavity. The compositions may comprise drugs including anesthetics, antihistamines and mixtures thereof. Anesthetics include lidocaine hydrochloride and antihistamines include diphenhydramine hydrochloride (claims 2-3). The pH the compositions may range from 3 to 10 (see Abstract). The reference differs from the instant claims insofar as it does not disclose the ratio of local anesthetic and an antihistamine when used in a composition together.

The claims read on a 1:1 ratio of anesthetic and the antihistamine. The term “mixtures” is generally understood to be 1:1. In any case, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. See MPEP 2144.05, II. It would have been obvious to one of ordinary skill in the art to have added the two components in a 1:1 ratio or adjusted the amounts accordingly motivated by the desire to deliver the agents to obtain optimal efficacy to treat the targeted disease or condition, as supported by the MPEP.

Claims 15-20 and 22-34 are rejected.

No claims allowed.

Conclusion

² Nishibe et al. US 2003/0008019, paragraph 0011.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612